**ORIGINAL** 

## 88130000159 8EHQ-13- 19001 2/26/13 COMMENTS:

**DOES NOT CONTAIN CBI** 



The Chemical Company

2313 FEB 25 7719:58

February 25, 2013



## Via Federal Express

United States Environmental Protection Agency - East Attn: TSCA Section 8(e) Room 6428 1201 Constitution Avenue, NW Washington, DC 20004



Subject: Notice in Accordance with TSCA Section 8(e): Results of a Combined Repeated Dose Toxicity Study with Reproduction / Developmental Toxicity Screening Test in CD rats with Butanedioic acid, sulfo-, 1-C12-18-alkyl esters, disodium salts, CAS No. 90268-36-3

Dear Section 8(e) Coordinator:

BASF Corporation is submitting results of a Combined Repeated Dose Toxicity Study with Reproduction / Developmental Toxicity Screening Test in CD rats [Crl:CD(SD)] with Butanedioic acid, sulfo-, 1-C12-18-alkyl esters, disodium salts, CAS No. 90268-36-3 conducted by LPT, Hamburg, Germany on behalf of BASF SE, Ludwigshafen, Germany. The test substance is an emulsifier used in cosmetics.

The test substance was administered to groups of 10 male and 10 female CD rats via gayage beginning 2 weeks before mating and for males continuing until a minimum dosing period of 28 days was completed and for females continuing up to, and including, day 3 postpartum. After completion of dosing period animals were sacrifice and pathology and histopathology as well as hematological parameter and clinical chemistry were recorded. During the experiment clinical signs, reproductive performance, clinical chemistry etc. are recorded. The study was performed according to OECD 422 guidelines

The dose levels were: 300, 120, and 60 mg/kg body weight/day

## The following findings were observed (interim results of the study): 300 mg/kg:

- 1male & 1female premature death
- only 3out of 9 females with litters
- bw decrease vs control on day 15: 10% in males; 5.5% in females
- bw decrease vs control on day 29: 16% in males; on day 42: 13% in males

## 120 mg/kg:

slight body weight decreases in males day 8, 22, 29, 42 (<10% versus control)

60 mg/kg: so far no changes

CONTAINS NO CBI

**BASF Corporation** 100 Park Avenue Florham Park, NJ, 07932 Tel: (800) 526-1072 www.basf.com/usa



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BASF Corporation understands that reporting of the results from this study under TSCA 8(e) is in accordance with EPA's policy.

Please note the technical contact and address below and direct all correspondence negarding this submission accordingly. If you have any questions, please call (248) 948-2051.

Sincerely,

**Technical Contact:** 

Alisa Boucher

BASF Corporation

alisa Boucher

Product Regulatory Center of Expertise - North America

26701 Telegraph Road, Southfield, MI 48033

/enclosures

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From: (248) 948-2051 Alisa Boucher BASE

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SOUTHFIELD, MI 48033

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**WASHINGTON, DC 20004** 

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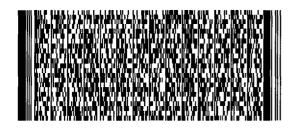
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